

KO 11941

AUG 22 2001

EXHIBIT # 12

510(k) Summary

**Kendall Excilon® A.M.D. Antimicrobial Sponges**

In accordance with section 513(l) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

The Kendall Company / Division of Tyco Healthcare  
15 Hampshire Street  
Mansfield, MA 02048  
Date Prepared: June 20, 2001

1. Contact Person

Michael P. Spears  
Regulatory Affairs Specialist  
Phone - (508) 261-8155  
Fax - (508) 261-8461

2. Name of Medical Device

Proprietary Name:	Excilon® A.M.D. Antimicrobial Sponges
Common Name:	wound dressing
Classification Name:	dressing

3. Identification of Legally Marketed Device

The proposed Kendall Excilon® A.M.D. Antimicrobial Sponge is substantially equivalent in intended use, function and composition to the Kendall Kerlix AMD Antimicrobial Gauze, 510(k) No. K990530 and the Acticoat® Primary Antimicrobial Dressing, 510(k) No. K992221.

4. Device Description

The proposed Kendall Excilon® A.M.D. Antimicrobial Sponge is a sterile, single use wound dressing consisting of nonwoven material treated with Cosmocil®CQ. Polyhexamethylene Biguanide Hydrochloride (PHMB) is the active ingredient in Cosmocil®CQ. The sponges have a slit cut in them from the center of one side up through the midpoint where a T-cut is formed. The dressing is packaged in a paper paper pouch and will be available in 2" x 2" and 4" x 4" sponge form.

K 0 11941

5. Device Intended Use

Excilon® A.M.D. Antimicrobial Sponges are intended for use as primary dressings for IV sites, Tracheostomy tube sites, chest tube sites, catheter sites and drain sites. The antimicrobial activity of the PHMB in Excilon® A.M.D. helps to resist bacterial colonization of the dressing and inhibit bacterial penetration through the dressing. The barrier function of the dressing may help reduce infections in partial and full thickness wounds.

6. Product Comparison

The Kendall Excilon® A.M.D. Antimicrobial Sponge is equivalent to the referenced predicate devices in that they are intended to be used as wound dressings. They each contain an ingredient that enhances the bacterial barrier function of the dressings and each has a broad spectrum of antimicrobial activity.

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 22 2001

Mr. Michael P. Spears  
Regulatory Affairs Specialist  
The Kendall Company  
Division of Tyco Healthcare Group  
15 Hampshire Street  
Mansfield, Massachusetts 02048

Re: K011941

Trade/Device Name: Excilon A.M.D. Antimicrobial Sponge  
Regulatory Class: Unclassified  
Product Code: EFQ  
Dated: June 20, 2001  
Received: June 21, 2001

Dear Mr. Spears:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

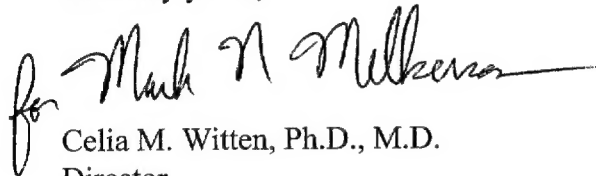
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Michael P. Spears

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Milken".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K011941

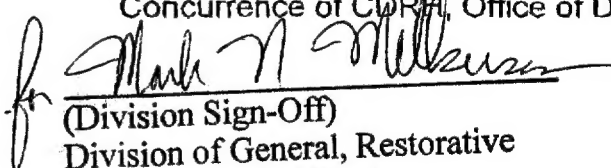
Device Name: Excilon A.M.D. Antimicrobial Sponge

Indications For Use:

Primary dressing for IV sites, tracheostomy tube sites, chest tube sites, catheter and drain sites.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRA, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K011941

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use     

(Optional Format 1-2-96)